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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/373,352	08/12/1999	DAVID EMIL EDGREN	ARC2247R1	2512

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EXAMINER
CHOI, FRANK I

ART UNIT	PAPER NUMBER
1616	

DATE MAILED: 05/08/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/373,352	Applicant(s) EDGREN ET AL.	
	Examiner Frank I Choi	Art Unit 1616	

-- The MAILING DATE of this communication appears on th cover sh et with the correspond nce address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 February 2002* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *19-36* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *19-36* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Examiner has duly considered Applicant's arguments but deems them moot in light of the new grounds of rejection herein.

Election/Restrictions

Applicant has cancelled claims 1,2,5-15,18 such that claims directed to a dosage form containing a core surrounded by two membranes and have added new claims 21-36 which appear to be directed to a similar invention. In light of the cancellation of the claims directed to membranes per se, Examiner withdraws the election of species requirement and has considered the claims in their entirety.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 21-36 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential elements, such omission amounting to a gap between the elements or necessary structural connections. See MPEP § 2172.01. The claims omit one or more of the following elements. The Specification appears to indicate that a drug, interior membrane formed around the core comprising a polymer possessing a lipophilic-attracting property and flux enhancer and a exterior membrane formed around the interior membrane comprising a polymer permeable to the passage of an aqueous fluid and a plasticizer are essential (See Specification, pg. 6-12. As such, said elements should be in claim 21 in addition to the peptide.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 19-28, 30, 32-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pozzi et al. (US Pat. 5,629,017) in view of Benton et al. (US Pat. 4,876,094) and Oshlack et al. (US Pat. 5,356,467).

Pozzi et al. teaches a dosage form comprising a core containing drug coated by a hydrophobic layer containing fats or waxes, such as carnauba wax, beeswax, hydrogenated castor oil, petroleum wax and mixtures of mono-,di- and tri-glycerides of polyeth ylene glycol, and a water-soluble film forming material, such as hydroxyalkyl-celluloses, in an amount of about between 5 and 30% of the hydrophobic material and a surfactant, such as ethoxylated fatty alcohols, in an amount of about 5 to 20% of the hydrophobic material (Columns 3, 4). It is taught that the hydrophobic layer can be coated by a polymeric enteric coating such as cellulose acetate phthalate, methacrylic acid-methacryoic acid ester copolymers, HPMC phthalate, polyvinyl acetate phthalate, hydroxyethylcellulose phthalate and cellulose acetate tetraphalate to which a plasticizer can be added (Column 6, lines 52-68).

Benton teaches dual coated dosage forms comprising a core containing a drug, a hydrophobic layer containing fats and a second layer contain zein to which a plasticizer can be added (Columns 3, 4). It is taught that the second coat enables the dosage form to be solubilize only in a limited pH range found in the GI tract. (Column 51-56).

Oshlack et al. (US Pat. 5,356,467) teaches that the release properties of zein containing coatings can be further adjusted to a desired rate by use of hydrophilic polymers (Column 8,

lines 53-68). It is taught that the controlled release coating can include an exit means comprising at least one passageway (Column 9, lines 66-68, Column 10, lines 1-12).

The difference between the prior art and the claimed invention is that the prior art does not expressly disclose a dosage form containing a core, lipophilic layer and hydrophilic layer containing a peptide. However, the prior art amply suggests the same as dosage forms containing lipophilic and hydrophilic layers and coating membranes containing zein are known in the art. As such, it would have been well within the skill of one of ordinary skill in the art to modify the prior art as above with the expectation of obtaining a dosage form which can be formulated to deliver drug in the GI tract as desired.

Therefore, the claimed invention, as a whole, would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, because every element of the invention has been collectively taught by the combined teachings of the references.

Claims 19-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zeitoun et al. (U.S. Pat. 4,432,966) over Seminoff et al. (U.S. Pat. 5,126,146), Staniforth (US Pat. 5,504,614) and Oshlack et al. (US Pat. 5,356,467).

Zeitoun et al. teach a dosage form containing a core containing a drug coated with a first layer containing ethyl cellulose which is covered by an enteric coating such as cellulose acetylphthalate, hydroxypropylmethylcellulose phathalte, keratin, and plasticizers (Columns 1,2).

Seminoff et al. teach that flux regulators and surfactants can be added ethyl cellulose coatings to achieve the desired permeability and improve blending and dispersion of the polymer, respectively (Columns 3, 4).

Staniforth teaches that the rate of release can be modified by making an orifice in the coated device and the use of swelling agents (Column 9)

Oshlack et al. is cited here for the same reasons as above and incorporated herein to avoid repetition.

The difference between the prior art and the claimed invention is that the prior art does not expressly disclose a dosage form containing a core, lipophilic layer and hydrophilic layer containing a peptide. However, the prior art amply suggests the same as dosage forms containing lipophilic and hydrophilic layers and coating membranes containing zein are known in the art. As such, it would have been well within the skill of one of ordinary skill in the art to modify the prior art as above with the expectation of obtaining a dosage form which can be formulated to deliver drug in the GI tract as desired.

Therefore, the claimed invention, as a whole, would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, because every element of the invention has been collectively taught by the combined teachings of the references.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

A facsimile center has been established in Technology Center 1600. The hours of operation are Monday through Friday, 8:45 AM to 4:45 PM. The telecopier numbers for accessing the facsimile machines are (703) 308-4556 or (703) 305-3592.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frank Choi whose telephone number is (703) 308-0067. Examiner maintains a flexible schedule. However, Examiner may generally be reached Monday-Friday, 8:00 am – 5:30 pm (EST), except the first Friday of the each biweek which is Examiner's normally scheduled day off.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, Mr. José Dees, can be reached on (703) 308-4628. Additionally, Technology Center 1600's Receptionist and Customer Service can be reached at (703) 308-1235 and (703) 308-0198, respectively.

FIC
5/6/2002

JOHN PAK
PRIMARY EXAMINER
GROUP 1600